APR 1 2 2002

510(k) SUMMARY

K020219

This 510(k) summary is being submitted in accordance with the requirements of SMDA and21CFR § 807.92

I. NAME OF SUBMITTER

RPI
Replacement Parts Industries, Inc.
P.O. Box 5019
Chatsworth, California
91313-5019

Phone Number: (818) 882-8611

Contact Person
Ira Lapides, President/CEO

Date Prepared: January 4, 2002

II. DEVICE NAME AND CLASSIFICATION

Proprietary Name:	RPI Skin and Air Temperature Probes
Common or Usual Name:	Skin and Air Temperature Probes
Classification:	Class II, 21 CFR 880.5130, Infant Radiant Warmers

III. PREDICATE DEVICES

The RPI Temperature Probes are substantially equivalent in design and indications for use to the following devices currently in commercial distribution:

- Accutemp-Probe, Kentec Medical, Inc., 510(k) number K970686
- Hill-Rom ISOLETTE Infant Incubator; Hill-Rom Air-Shields, Hatboro, PA 19040; 510(k) number K001242
- First Touch Disposables Temperature Probes, First Touch Disposables, Inc., Wilmington, NC 28403; 510(k) number K950422

IV. DESCRIPTION

The RPI Temperature Probes are intended to be used as replacement parts for Air Shields infant radiant warmers and infant incubators. The RPI Temperature Probes are used to monitor the patient's skin temperature or the unit's air temperature when used in conjunction with the infant radiant warmer or infant incubator. The probes are connected to a unit controller to automatically adjust the heater output of the unit to maintain a pre-selected skin

or air temperatue. Two of the probes are used in "baby-controlled mode" to monitor the skin temperature of the baby and one of the probes is designed to be used in "air controlled mode", to monitor the air temperature of the incubator or radiant warmer. One probe is a disposable skin temperature probe.

The RPI Skin Temperature Probes have a thermistor tip which is attached to the infant's skin. A cable attaches the probe to the unit controller. The electrical flow resistance changes in response to changes in the skin temperature. This resistance change is converted into a temperature reading. The Skin Temperature Probe is available in three models, including a disposable probe and a reusable probe. The Air Temperature Probe has the same thermistor tip, which is attached to a cable connecting the probe to the controller. The Temperature Probes are provided nonsterile.

V. INTENDED USE

RPI Temperature Probes are designed to be used as replacement temperature sensing probes for use with the temperature controller portion of Air Shields infant radiant warmers and infant incubators. The probes provide temperature feedback in order to maintain pre-selected temperature settings.

VI. TECHNOLOGICAL CHARACTERISTICS

No new technology, materials, or change in efficacy have been introduced by RPI in the manufacture of the RPI Temperature Probes. The design, form, and materials of the probes are equivalent to their predicate devices in that all are designed to be used to sense temperature information when in the skin or air sensing modes and to feed this information to the controller of the incubator or radiant warmer. All devices are provided nonsterile to the user. The RPI Temperature Probe and its predicate devices are available as reusable devices or as disposable devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 12 2002

Mr. Ira Lapides
President
Replacement Parts Industries, Incorporated
P.O. Box 5019
Chatsworth, California 91313-5019

Re: K020219
Trade/Device Name: RPI Replacement Temperature Probes
Regulation Number: 880.5130
Regulation Name: Infant Radiant Warmer
Regulatory Class: II
Product Code: FMT
Dated: January 16, 2002
Received: January 22, 2002

Dear Mr. Lapides

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Include the following "Indications For Use" page that contains the applicant's name, name of the device and the intended use of the device. The information, data and labeling claims in the entire the 510(k) submission must support and agree with the "indications for use" statement.
*For a new submission, do NOT fill in the 510(k) number blank.

INDICATIONS FOR USE

Applicant: Replacement Parts Industries, Inc. (RPI, Inc.)

510(k) Number (if known): ~~N/A~~* K020219

Device Name: RPI Replacement Temperature Probes

Indications For Use:

RPI Skin or Air Temperature Probes are designed to be used as replacement temperature sensing probes for use with the temperature controller portion of Air Shields infant radiant warmers and infant incubators. The probes provide skin or air temperature feedback in order to maintain pre-selected temperature settings.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter _____
Per 21 CFR 801.109

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020219